UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JENNIFER L. HILLMAN, PREETI LAL, Y. TOM TANG, HENRY YUE, and NEIL C. CORLEY

Application No. 09/036,614

ORDER UNDER 37 CFR § 41.50(d)

Before WILLIAM F. SMITH, ADAMS and GRIMES, <u>Administrative Patent Judges</u>.

ADAMS, <u>Administrative Patent Judge</u>.

ORDER UNDER 37 CFR § 41.50(d)

Under the provisions of 37 CFR § 41.50(d),¹ we require Appellants to address the following matters:

<u>First</u>, we invite attention to commonly assigned Application No. 09/078,402 where, according to Patent and Trademark Office (PTO) records, the applicants filed a Notice of Appeal from the examiner's final rejection on June 25, 2001.² After a briefing stage, another Merits Panel of the Board handed down its decision in the '402

¹ "The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order." 37 CFR § 41.50(d).

² The named inventors in the instant application are Jennifer L. Hillman, Preeti Lal, Y. Tom Tang, Henry Yue, and Neil C. Corley. In Application No. 09/078,402, the inventors are Jennifer Hillman, Neil C. Corley, Karl J. Guegler, Chandra Patterson and Mariah Baughn. The applications are commonly assigned.

application, affirming the examiner's final rejection of claims 3, 6, 7, 9-12, and 19-24 (Appeal No. 2003-1115, BPAI 2004).

We think it clear that Appeal No. 2003-1115, in Application No. 09/078,402, bears close relationship to the instant appeal. In Appeal No. 2003-1115, the claims are drawn, inter alia, to an isolated polynucleotide encoding a polypeptide comprising an amino acid sequence selected from the group consisting of: SEQ ID NO:3; residues 31 through 40 of SEQ ID NO:3; and SEQ ID NO:5 (claims 3, 6, 7, 9, 10, and 21), host cells and methods of making the encoded proteins (claims 11 and 12). Included among the issues presented for appeal was whether the applicants' claims were supported by a disclosure of utility sufficient to satisfy 35 U.S.C. § 101.

In Appeal No. 2003-1115, Appellants asserted that "the claimed invention ha[d] numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of diseases..., none of which requires knowledge of how the polypeptide coded for by the polynucleotide actually functions." Decision, page 12. In addition, Appellants argued that the claimed polynucleotides are useful in, among other things, "gene and protein expression monitoring applications." Id. Appellants relied on the declaration of Dr. Tod Bedilion to support their argument that the claimed polynucleotides have patentable utility because they can be used to monitor gene expression. See e.g., Decision, pages 12-15. Further, Appellants relied upon sequence similarity between the protein encoded by the claimed polynucleotide and proteins known in the art to support their assertion that "one skilled in the art would have no doubt that the claimed polynucleotides are homologues of ... [the known proteins]."

Decision, bridging sentence, pages 16-17.

The previous Merits Panel reviewed governing principles of law; the Bedilion Declaration; and addressed and rejected the applicants' arguments, concluding that "[a]ppellants' disclosure in th[at] case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." Decision, page 28. Accordingly, the rejection of all claims under 35 U.S.C. § 101 in Application No. 09/078,402, was affirmed.

Like the claims in Application No. 09/078,402, the claims in this appeal are drawn to isolated polynucleotides (claims 22-25, 28 and 29), a cell transformed with a polynucleotide of claim 25 (claim 26), and a method of producing a polypeptide encoded by the polynucleotide of claim 22 (claim 27). All of the appealed claims stand rejected under 35 U.S.C. § 101 "because the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility." Answer, page 4.

The Appeal Brief in this appeal includes essentially the same line of argument addressed by the previous Merits Panel in Appeal No. 2003-1115 (Appeal Brief, section (8)). For example, Appellants argue "the claimed invention has numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease, none of which requires knowledge of how the polypeptide coded for by the polynucleotide actually functions" (id., bridging paragraph, pages 3-4). Appellants rely on the Bedilion Declaration to support their assertion that the claimed invention has use in gene and protein expression monitoring applications. Id. pages 4, and 7-10. In

addition, Appellants emphasize the percent sequence identity that the polypeptide encoded for by the claimed polynucleotide shares with kinesin light chain.³

On these facts, we require that Appellants explain why we should address these arguments anew in this case. Since these same issues have been raised previously in Appeal No. 2003-1115, why would the previous Panel's treatment of these issues not be dispositive here? In particular, why should the facts and arguments set forth in Appellants' Appeal Brief lead to a different conclusion than that reached by another Panel in Appeal No. 2003-1115 rejecting the same line of argument? We note in passing that the Appellants did not request rehearing on the same record within two months from the date of the decision in Appeal No. 2003-1115. Rather, according to PTO records, the application was abandoned.

Second, Appellants state that "[t]here is no dispute that the claimed invention is in fact a useful tool in cDNA microarrays used to perform gene expression analysis." Brief, page 7. However, the assertion that "[t]here is no dispute that the claimed invention is in fact a useful tool" appears to be incorrect. See, e.g., Answer, page 27, wherein the examiner states "the assertion that the claimed polynucleotide has patentable utility as a probe in, or member of, a microarray is not specific." Accordingly, on this record, it appears that there is a dispute whether the claimed invention is a useful tool in cDNA microarrays.

Explanation or clarification of this apparent discrepancy is required.

³ According to Appellants' disclosure (page 2), "[t]he prototypical kinesin molecule is a heterotetramer comprised of two heavy polypeptide chains (KHCs) and two light polypeptide chains (KLCs)." Appellants admit, however, "[t]he precise contribution of KLC to kinesin function is unknown." Specification, page 3.

Third, according to Appellants "[I]iterature reviews published shortly after the filing of the ...[instant] application describing the state of the art further confirm the claimed invention's utility." Brief, page 10. In this regard, Appellants cite references authored by Rockett et al., Steiner et al., and Nuwaysir et al. having publication dates in 1999, 2000, and 1999, respectively (id., pages 10-12). We note that the instant application was filed March 7, 1998.

Explanation is required how the cited references would provide evidence that, <u>as</u> of the effective filing date of the present application, those of skill in the art would have recognized the asserted utilities as well-established.

Fourth, based on our review of the image file wrapper, we do not find any indication in the record that Appellants have submitted into the record:

- the April 9, 2000, article published by the Bloomberg News Service (Appeal Brief, pages 12-13);
 - the February 10, 2000, article in the <u>Wall Street Journal</u> (<u>id.</u>, page 13); or
 - evidence reflecting the work by C.V. Therapeutics (id., page 12).4

Accordingly, explanation or clarification is required respecting just what evidence is of record which would support Appellants' argument in the Appeal Brief, pages 12-13.

Conclusion

In conclusion, we require Appellants to address the foregoing matters "deemed appropriate for a reasoned decision on the pending appeal." 37 CFR § 41.50(d)(2003).

⁴ Generally speaking, the submission of evidence after a case has been appealed would be considered untimely. As stated in the then existing 37 CFR § 1.195 (2003), "[a]ffidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented."

We caution, however, that this is not an invitation to expand on points raised in the Appeal Brief or to rehash arguments already set forth in the Appeal Brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2003-1115. See 37 CFR § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Appellants' response should be confined to the matters outlined above.

Time Period For Response

A period of one month from the date of this order is set for Appellants' response.

This time is non-extendable.

Failure to respond in a timely manner will result in dismissal of the appeal.

37 CFR § 41.50(d)

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

BOARD OF PATENT

APPEALS AND

INTERFERENCES

Eric Grimes

Administrative Patent Judge

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